REMARKS

This submission is in response to the Official Action dated October 22, 2002. Claims 1, 5, 8, 9, 19 and 21 have been amended. Claims 6 and 7 have been canceled, without prejudice or disclaimer. New claims 22-29 have been added. Claims 1-5 and 8-29 are pending upon entry of this amendment. Reconsideration of the above identified application, in view of the above amendments and the following remarks, is respectfully requested.

Claim 1 has been amended to recite "an enzymatically active fragment thereof." Support for an enzymatically active fragment of C2/4GnT can be found on page 4 lines 9-24, page 3 lines 26-28, page 10 lines 13-16, and page 20 lines 19-22. Claim 1 has also been amended to recite that C2/4GnT has the amino acid sequence of SEQ ID NO:2. Support for this amendment can be found throughout the specification and, in particular, on page 3 lines 24-26, page 4 lines 20-27 and page 5 lines 11-17.

Claim 21 has been amended to recite "wherein the amplified genomic regions are at least 95% identical to SEQ ID NO: 1." Support for this amendment can be found on page 9 lines 7-8, and page 19 lines 10-11.

Claims 22-29 are new. Support for new claim 22 can be found throughout the specification and in particular on page 3 lines 17-19, page 3 lines

24-26 and Figure 2 (please note that as demonstrated in Figure 2 and in SEQ ID NO: 1 in the Sequence Listing, nucleotides 496-1812 of SEQ ID NO:1 correspond to amino acids 1-438 of SEQ ID NO: 2). Support for claim 24 can be found in original claim 21, page 9 lines 9-10, page 19 lines 12-13 and page 4 lines 28-33. Support for new claim 23 can be found throughout the specification and, in particular, on page 3 lines 26-28, page 4 lines 9-11, page 10 lines 13-16 and page 20 lines 19-22 (please note that as demonstrated in Figure 2 and in SEQ ID NO: 1 in the Sequence Listing, nucleotides 634-1812 of SEQ ID NO:1 correspond to amino acids 31-438 of SEQ ID NO:2).

Support for new claim 24 can be found on page 9 lines 7-8, page 4 lines 28-33, page 19 lines 10-11, and page 22 lines 20-24. Support for new claims 25 and 26 can be found on page 3 lines 29-32 and page 14 lines 20-34. Support for new claim 27 can be found throughout the specification and, in particular, on page 4 lines 2-14 and Example 2 (page 20 lines 17-29). Support for new claims 28 and 29 can be found on page 3 line 32 - page 4 line 16, page 10 lines 19-25 and Example 2 (page 20 lines 17-29). No new matter has been added by way of these amendments.

SEQUENCE COMPLIANCE

The Examiner noted that neither Figures 2 and 3 nor their description in the specification provided SEQ ID NOS to the sequences depicted in these figures. Accordingly, Applicants have herein amended the description of Figures 2 and 3 in the specification to refer to the SEQ ID NOS depicted in these figures. Specifically, the specification has been amended so that the description of Figure 2 in the Brief Description of the Drawings section of the specification refers to the sequences shown in Figure 1 (SEQ ID NOS: 1 and 2). Likewise, the specification has also been amended so that the description of Figure 3 in the Brief Description of the Drawings section of the specification refers to the sequences shown in Figure 3 (SEQ ID NOS: 11, 2 and 12). No new matter has been added by way of this amendment. Upon submission of formal drawings, the SEQ ID NOS of each of the sequences of Figures 2 and 3 will also be indicated on their respective Figures.

SEQ ID NOS: 11 and 12 were not listed in the previously filed Sequence Listing. Accordingly, this amendment and response is accompanied by a paper and computer readable form (CFR) of a substitute Sequence Listing.

STATEMENT PURSUANT TO 37 C.F.R. § 1.821

Enclosed herewith is a paper copy and computer readable form

(diskette) containing sequence disclosures. Pursuant to 37 C.F.R. § 1.821, Applicants hereby confirm that the contents of the paper copy of the substitute Sequence Listing filed herewith and entitled "SEQUENCE LISTING", and of the identically labeled diskette enclosed herewith, specifically the ASCII-encoded file therein labeled "Seqlist.txt", are identical. This sequence submission contains no new matter.

Consideration of the enclosed diskette and paper copy of a Substitute Sequence listing, are respectfully requested.

REJECTION UNDER 35 U.S.C. § 101

Claim 7 was rejected by the Examiner for allegedly being directed to a non-statutory subject matter. Claim 7 has been cancelled, without prejudice or disclaimer. Accordingly, this rejection is moot.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner rejected claims 1 (and its dependent claims 2-5), 8, and 10-21 as allegedly indefinite because of the phrase "C2/4GnT." Specifically, the Examiner contends that it is unclear whether the slash between core 2 and core 4 indicates that C2/4GnT has core 2 *or* core 4 activity or whether the entire

polypeptide has core 2 *and* core 4 activity.

Applicants respectfully disagree. The C2/4GnT enzyme is discussed throughout the application as having both core 2 *and* core 4 activity. Applicants point the Examiner specifically to page 1 lines 7-12, page 2 line 30 - page 3 line 4, page 8 lines 18-20, and page 11 lines 24-25 of the specification for descriptions of C2/4GnT's activity. Thus, as is disclosed in the application, this enzyme can be used in the formation of one or both of core 2 and core 4-based O-glycan modification on oligosaccharides, glycoproteins, and glycosphinolipids. One skilled in the art would readily understand from the specification that C2/4GnT has both core 2 and core 4 activity. Accordingly, the enzyme has been appropriately termed UDP-N-acetylglucosamine: galactose- 1,3-N-acetylgalactosamine- -R / N-acetylglucosamine- 1,3-N-acetylgalactosamine- -R 1,6-N-acetylglucosaminyltransferase (C2/4GnT) to indicate that it has both C2 and C4 activity. Thus, Applicants believe the meaning of C2/4GnT to be well-defined in the specification and respectfully request that this rejection be withdrawn.

The Examiner also rejected claim 6 for alleged indefiniteness. Claim 6 has been cancelled, without prejudice or disclaimer. Accordingly, this rejection is moot.

The Examiner also rejected claim 21 for alleged indefiniteness

because of the phrase "β C2/4GnT." Specifically, the Examiner contended that it was not clear whether "β C2/4GnT" was the same or different from "C2/4GnT." "β" has been deleted from this phrase and, thus, this rejection has been overcome. Accordingly, Applicants respectfully request withdrawal of this rejection.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-4, 6, 8, 11, 14-19 and 21 have been rejected for allegedly not being enabled by the specification. The Examiner acknowledges that DNA with SEQ ID NO:1 encoding a protein with SEQ ID NO:2 having C2 and C4 GnT activity is enabled. However, the Examiner contends that claims 1-4, 6, 8, 11, 14-19 and 21 encompass any DNA encoding a polypeptide having a combined C2 and C4 GnT activity and that sufficient guidance has not been provided in the specification for one skilled in the art to make and use these DNAs. By the present amendment, claim 1 clearly encompasses only those polynucleotides encoding the polypeptide of SEQ ID NO: 2 or fragments of said polypeptide having enzymatic activity. Accordingly, Applicants request withdrawal of this rejection.

REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-4, 6-8, 11 and 15 have been rejected for allegedly being

anticipated by Adams et al. (GenBank Accession No. AA315469) or NCI-CGAP (GenBank Accession No. AA583339).

Applicants respectfully disagree. Claims 1-4, 8, 11 and 15 as amended recite nucleic acids encoding UDP-N-acetylglucosamine: galactose-β1,3-N-acetylgalactosamine-α-R / N-acetylglucosamine-β1,3-N-acetylgalactosamine-α-R β1,6-N-acetylglucosaminyltransferase (C2/4GnT) having the amino acid sequence SEQ ID NO:2 or an enzymatically active fragment of this transferase. Neither Adams et al. or NCI-CGAP disclose nucleic acids encoding SEQ ID NO:2 or an enzymatically active polypeptide; they merely disclose nucleotide sequences that are a part of the presently claimed C2/4GnT polynucleotide sequences. Specifically, Adams et al. discloses nucleotides 245-435 of SEQ ID NO: 1; these 190 nucleotides are in the 5' non-coding sequence of SEQ ID NO:1 and, thus, even in the context of proper transcription start and stop sequences, which they are not, these nucleotides would not even encode a single amino acid of C2/4GnT. NCI-CGAP discloses nucleotides 1624-2263 of SEQ ID NO:1; these 640 nucleotides, even in the context of proper transcriptional start and stop sequences, which they are not, would only encode the last 62 amino acids of C2/4GnT's 438 amino acids. Thus, neither sequence would encode a polypeptide

with enzymatic, specifically C2/4GnT activity.

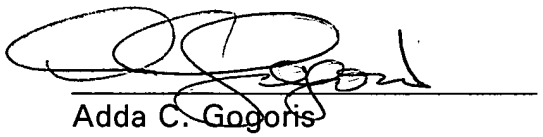
Neither Adams et al. or NCI-CGAP encodes the claimed enzyme UDP-N-acetylglucosamine: galactose-β1,3-N-acetylgalactosamine-α-R / N-acetylglucosamine-β1,3-N-acetylgalactosamine-α-R β1,6-N-acetylglucosaminyltransferase (C2/4GnT) or an enzymatically active fragment of this enzyme. Neither of these references discloses all elements of the claimed invention and, thus, neither of these references anticipates the pending claims. Accordingly, Applicants respectfully request withdrawal of this rejection.

CONCLUSION

Therefore, in view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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EXPRESS MAIL CERTIFICATE

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I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

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PATENT TRADEMARK OFFICE

Docket No: 4305/0J425

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henrik Clausen; Tilo Schwientek

Serial No.: 09/874,390 Art Unit: 1652

Confirmation No.: 5094

Filed: June 4, 2001 Examiner: RAO, Manjunath

For: UDP-N-Acetylglucosamine: Galactose-B1,3-N-Acetylgalactosamine ...

MARK-UP AMENDMENT PURSUANT TO § 1.121

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

January 22, 2003

Sir:

IN THE SPECIFICATION:

Please amend the paragraph on page 5 lines 11-17 in the "Brief Description of the Drawings" section of the specification to read as follows:

Figure 2 depicts the DNA sequence of the C2/4GnT (SEQ ID NO:1; accession # AF038650) gene and the predicted amino acid sequence of C2/4GnT (SEQ ID NO:2). The amino acid sequence is shown in single letter code. The hydrophobic segment representing the putative transmembrane domain is double underlined. Two consensus motifs for N-glycosylation are indicated by *asterisks*. The location of the primers used for preparation of the expression constructs are indicated by *single underlining*. A potential polyadenylation signal is indicated in *boldface underlined type*.

Please amend the paragraph on page 5 lines 18-24 in the "Brief Description of the Drawings" section of the specification to read as follows:

Figure 3 is an illustration of a sequence comparison between human C2GnT (SEQ ID NO:11; accession # M97347), human C2/4GnT (SEQ ID NO:2; accession # AF038650), and human I-GnT (SEQ ID NO:12; accession # Z19550). Introduced gaps are shown as *hyphens*, and aligned identical residues are *boxed* (*black* for all sequences, and *grey* for two sequences). The putative transmembrane domains are *underlined* with a *single line*. The positions of conserved cysteines are indicated by *asterisks*. One conserved N-glycosylation sites is indicated by an *open circle*.

IN THE CLAIMS:

Please amend the claims pursuant to 37 C.F.R. 1.121 as follows:

1. (Amended) An isolated nucleic acid encoding UDP-N-acetylglucosamine: galactose-β1,3-N-acetylgalactosamine-α-R / N-acetylglucosamine-β1,3-N-acetylgalactosamine-α-R β1,6-N-acetylglucosaminyltransferase (C2/4GnT) having the amino acid sequence SEQ. ID NO: 2 or [a] an enzymatically active fragment [hereof] thereof.

5. (Amended) An isolated nucleic acid [as defined in claim 1] encoding UDP-N-acetylglucosamine: galactose-β1,3-N-acetylgalactosamine-α-R/N-acetylglucosamine- β1,3-N-acetylgalactosamine-α-R β1,6-N-acetylglucosaminyl-transferase (C2/4GnT), wherein said nucleic acid comprises the sequence of nucleotides 1-2319 in SEQ ID NO:1 or sequence-conservative [or function-conservative] variants thereof.

8. (Amended) A nucleic acid vector comprising [a] the nucleic acid of claim 1 [sequence encoding C2/4GnT or fragments thereof].

9. (Amended) A vector as defined in claim 8, wherein said [sequence] nucleic acid comprises the nucleotide sequence of nucleotides 1-2319 in SEQ ID NO:1 or sequence-conservative [or function-conservative] variants thereof.

19. (Amended) A method for producing C2/4GnT polypeptides, which comprises:

(i) introducing into a host cell [an] the isolated nucleic acid of claim 1 or the nucleic acid vector of claim 8 [DNA molecule encoding a human C2/4GnT, or a DNA construct comprising a DNA sequence encoding C2/4GnT];

(ii) growing the host cell under conditions suitable for human C2/4GnT expression; and

(iii) isolating C2/4GnT produced by the host cell.

21. (Amended) A method for the identification of DNA sequence variations in the [β] C2/4GnT gene, comprising the steps of:

(i) isolating DNA from a patient;

(ii) amplifying C2/4GnT genomic regions by PCR, wherein the amplified genomic regions are at least 90% identical to SEQ ID NO: 1; and

(iii) detecting the presence of DNA sequence variation by DNA

sequencing, single-strand conformational polymorphism (SSCP) or mismatch mutation.